Remarks

These remarks respond to the Office Action of October 27, 2008. Citations to the specification refer to the original specification filed on September 12, 2001 and its page and line numbers, also published as WO 2000/055327A2.

Claims 25, 32, 35, 40, 41, 43, 60, 64, and 67 are allowed. Claims 29, 31, 50, 51, 57, 59, 62, 63, 65, 66, and 68-72 are rejected, and claim 61 is under objection.

By this amendment, claims 61 and 68 are canceled and claims 29, 31, 71, and 72 are amended to clarify that a "co-protein carrier" may be coupled to the polypeptide. Support for these amendments is found in the specification, for example, at page 62, line 19 to page 63, line 2. No new matter has been added.

Claim Objection

Claim 61 is under objection for depending from a canceled claim. Its cancellation renders this objection moot.

Written Description

Claims 29, 31, 50, 51, 57, 59, 62, 63, 65, 66, and 68-72 stand rejected under 35 U.S.C. § 112, first paragraph. This rejection is moot as to canceled claim 68 and should not be maintained against the remaining claims for the following reasons.

Claims 29, 31, 50, 51, 57, 59, 62, 63, 65, 66, and 69-72 call for a polypeptide comprising an immunogenic fragment of at least 15 or 20 contiguous amino acids of SEQ ID NO:2 capable of inducing an antibody that specifically binds to the fragment, which fragment may be coupled to a co-protein carrier. The M.P.E.P. Guidelines state that written description may be satisfied by disclosure of sufficiently detailed, relevant, identifying characteristics, such as complete or partial structure, other physical and/or chemical properties, functional characteristics coupled with a known or disclosed correlation between function and structure, or some combination of such identifying characteristics. For some biomoleculres, examples of identifying characteristics include a sequence. M.P.E.P. § 2163.II.A.3. The present specification provides proper and adequate description of the rejected claims according to the Guidelines.

The Office Action states that the claims are "inclusive to numerous structural variants." Office Action, October 27, 2008, at page 3, line 17. The rejection's reference to variants ignores applicants' definitions of fragments and variants, which are controlling. M.P.E.P. §2111.01 ("Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim."). Applicants' claims call for fragments, not variants. Variants are defined in the specification as "polypeptides that vary from the referents by conservative amino acid substitutions, whereby a residue is substituted by another with like characteristics." Specification at page 12, lines 12-14. A fragment is "a polypeptide having an amino acid sequence that is *entirely the same as part but not all* of any amino acid sequence of any polypeptide of the invention." Specification at page 9, lines 21-22 (emphasis added). Applicants' claims call for fragments, not variants. An immunogenic fragment as "a contiguous portion of the BASB082 polypeptide which has the same or substantially the same immunogenic activity as the polypeptide comprising the amino acid sequence of SEQ ID NO:2." Specification at page 5, lines 10-12. The sequence SEQ ID NO:2 defines the precise structure of the entire sequence as well as any fragments of contiguous amino acids within it.

The structures and functions of exemplary fragments are also described, such as those lacking an N-terminal leader sequence, a transmembrane domain, or a C-terminal anchor domain. Specification at page 5, lines 14-16. Other preferred fragments are characterized by structural or functional attributes such as fragments that comprise alpha-helix and alpha-helix forming regions, beta-sheet and beta-sheet-forming regions, turn and turn-forming regions, coil and coil-forming regions, hydrophilic regions, hydrophobic regions, alpha-amphipathic regions, beta-amphipathic regions, flexible regions, surface-forming regions, substrate binding regions, and high antigenic index regions. Specification at page 10, lines 5-10. Therefore, the specification provides the precise structure of the BASB082 polypeptide fragments and both structural and functional descriptions of exemplary fragments.

Applicants have disclosed the precise sequences of the claimed BASB082 polypeptide fragments and the structures and functions of preferred fragments. This description, along with the knowledge of protein conjugation and fusion and the established structural and functional relationships within the art, provides sufficient structure, properties, and functional characteristics to establish that applicants were in possession of what is claimed. Moreover, in light of the ample structural and functional description found in the specification, the rejection's

statements and conclusions to the contrary are simply inaccurate.[1] For this reason the rejection of claims 29, 31, 50, 51, 57, 59, 62, 63, 65, 66, and 69-72 as lacking written description should be withdrawn.

Enablement

Claims 29, 31, 50-51, 57, 59, 62-63, 65-66, and 68-72 also stand rejected under 35 U.S.C. § 112 on the ground that the application does not enable an isolated polypeptide comprising an immunogenic fragment of at least 15 or 20 amino acids of SEQ ID NO: 2 or fusion protein or immunogenic composition comprising said fragment. Office Action at page 5, lines 12-20. This rejection is moot as to canceled claim 68 and, for the reasons that follow, should not be maintained against the remaining claims.

Enablement turns on whether one of skill could make or use the invention without undue experimentation using the disclosure of the application and information known in the art. M.P.E.P. § 2164.01. "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" *In re Wands*, 858 F2d, 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed Cir. 1988).

Throughout the specification, one finds guidance as to how to prepare the claimed polypeptides. For example, beginning at page 47, line 5, one finds description of vectors, host cells, and expression systems, as well as methods, for preparing the claimed polypeptide fragments. Ways to make the polypeptide SEQ ID NO: 2 as well as its fragments as claimed include a variety of host cells genetically engineered to incorporate expression systems or portions thereof or polynucleotides of the invention. Specification at page 47, line 11 to page 49, line 20. Methods of making various compositions with the polypeptides, including immunogenic compositions, are described at page 61, line 12 to page 74, line 19. Preparation of fusion proteins is described at page 10, line 22 to page 12, line 11 and page 59, lines 15-16.

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[1] The rejection's statements that: (1) "[t]he specification does not place any structure, chemical or functional limitations on the fragments" (Office Action at page 3, lines 21-22); (2) "the specification and the claim do not provide any guidance on the structure of the polypeptide" (Office Action at page 3, lines 26-27); (3) "[a]pplicant has not disclosed any relevant, identifying characteristics, such as structure or other physical and/or chemical properties" (Office Action at page 4, lines 17-19); and (4) "[s]tructural features that could distinguish a '15 or 20 contiguous amino acids of SEQ ID NO: 2' polypeptide in the germs from others in the protein class are missing from the disclosure" (Office Action at page 4, lines 22-24) ignore the ample presence of the very matter they purport to deny.

With the sequences disclosed by the specification, using techniques known to the art, one of ordinary skill would be able to prepare any immunogenic fragment of at least 15 or at least 20 contiguous amino acids of SEQ ID NO: 2, as well as fusion proteins and immunogenic compositions comprising those fragments or fusion proteins.

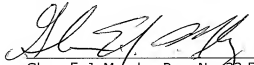
Exemplary methods for assessing antibody binding capabilities are taught by the specification at page 55, line 18 to page 59, line 4. Methods of producing and screening antibodies and inducing immunological responses in mammals are described at page 54, line 1 to page 55, line 17, at page 61, line 12 to page 62, line 18, and at page 66, line 19 to page 74, line 19. Such methods are well known in the art and may be practiced through commercially available kits and automated systems. Moreover, the specification provides guidance as to which fragments within SEQ ID NO: 2 are likely to be immunologically active. *See, e.g.,* page 10, lines 1-10. The specification thus teaches how to use known methods in the art to make and use the claimed immunogenic polypeptides and compositions comprising them without undue experimentation.

The rejection places much emphasis on unpredictability in the art and the quantity of experimentation; this emphasis is misplaced. As recognized in the rejection, the level of ordinary skill is high. Office Action at page 7, lines 3-4. There is no dispute that the methods of making the claimed polypeptides and screening them for immunological activity were known in the art and were within the capability of the skilled artisan. Even if the quantity of experimentation might be extensive, it is all routine, and therefore cannot be non-enabling. *See, e.g., Ex parte Kubin*, 83 U.S.P.Q.2d 1410, 1415-16 (Bd. Pat. App. & Int. 2007)(reversing finding of nonenablement of claims directed to polynucleotides encoding polypeptides having a specific binding affinity, even though the claims encompassed a large number of undefined modifications, the art was unpredictable, and the specification provided no guidance on which polypeptide residues were responsible for the binding affinity and no correlation between polypeptide structure and binding affinity). Therefore, one of ordinary skill in the art would be able to make and use the claimed polypeptide fragments, fusion proteins, and immunogenic compositions without undue experimentation, and the rejection of claims 29, 31, 50, 51, 57, 59, 62, 63, 65, 66, and 69-72 as not enabled should be withdrawn.

Conclusion

For the reasons stated above, it is respectfully submitted that the pending claims are in condition for immediate allowance, and a notice to this effect is solicited. The Examiner is invited to telephone Applicants' attorney if it is believed that a telephonic interview would expedite prosecution of the application.

Respectfully submitted,



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